



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0417; FRL-9301-01-OCSP]

Cyprodinil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyprodinil in or on multiple crops that are referenced later in this document. The Interregional Project Number 4 (IR-4) requested these tolerances under section 346a of the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0417, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns relating to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff

continues to provide customer service via email, phone, and webform. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the

instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2020-0417 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0417, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of June 28, 2021 (86 FR 33922) (FRL-10025-08) EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3),

announcing the filing of a pesticide petition (PP 0E8846) by IR-4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested that 40 CFR 180.532 be amended by establishing tolerances for residues of Cyprodinil, 4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine, in or on the raw agricultural commodities: *Brassica*, leafy greens, subgroup 4-16B, except watercress at 10 parts per million (ppm); Celtuce at 30 ppm; Fennel, Florence, fresh leaves and stalk at 30 ppm; Kohlrabi at 1 ppm; Leaf petiole vegetable subgroup 22B at 30 ppm; Leafy greens subgroup 4-16A, except parsley, fresh leaves at 50 ppm; Lemon/lime subgroup 10-10B at 0.6 ppm; Sugar apple at 4 ppm; Tropical and subtropical, small fruit, inedible peel, subgroup 24A at 2 ppm; and Vegetable, *Brassica*, head and stem, group 5-16 at 1 ppm. The petition also requested to remove established tolerances for residues of Cyprodinil, 4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine, in or on the raw agricultural commodities: *Brassica*, head and stem, subgroup 5A at 1.0 ppm; *Brassica*, leafy greens, subgroup 5B at 10.0 ppm; Leaf petioles subgroup 4B at 30 ppm; Leafy greens subgroup 4A at 50 ppm; Lemon at 0.60 ppm; Lime at 0.60 ppm; Longan at 2.0 ppm; Lychee at 2.0 ppm; Spanish lime at 2.0 ppm; and Turnip, greens at 10.0 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the commodity definition for one of the crop groups. A discussion of this modification can be found in section IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there

is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyprodinil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyprodinil follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for cyprodinil in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to cyprodinil and established tolerances for residues of that chemical. EPA is incorporating previously published

sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of cyprodinil, see Unit III.A. of the July 21, 2016 final rulemaking (81 FR 47304) (FRL-9948-28).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for cyprodinil used for human risk assessment, please reference Unit III.B. of the August 17, 2012 rulemaking (77 FR 49732) (FRL-9359-7). The table in the August 17, 2012 rulemaking included an endpoint for inhalation short-term exposures. However, the Agency has made the assumption in the current assessment that cyprodinil products are not for homeowner use, has not conducted a quantitative residential handler assessment as in previous reviews, and did not use the inhalation endpoint.

Exposure assessment. Much of the exposure assessment remains the same although updates have occurred to accommodate exposures from the petitioned-for tolerance and reflect changes to the residential exposure assessment. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, please reference Unit III.C. of the July 21, 2016 rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposure from the new use of cyprodinil on sugar apple and the crop group conversions and expansions requested in this action. Partially refined acute and chronic aggregate dietary (food and drinking water) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. The assessments used established and recommended tolerance-level residues for some commodities, average field trial residues for the remaining commodities (chronic only), 100 percent crop treated (PCT), and

EPA's 2018 default processing factors (except for potato granules/flakes, potato flour, tomato paste, tomato puree, lemon juice, apple juice, dried prune plum, and grape juice).

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Drinking water exposure. The new use does not result in an increase in the estimated residue levels in drinking water, so EPA used the same estimated drinking water concentrations in the acute and chronic dietary assessments as identified in the July 2016 rulemaking.

Non-occupational exposure. The previous review included a residential handler assessment which is no longer applicable. All registered cyprodinil product labels with residential use sites require that handlers wear specific clothing (e.g., long sleeve shirt/long pants) and/or use personal protective equipment (PPE). Therefore, the Agency has made the assumption that these products are not for homeowner use and has not conducted a quantitative residential handler assessment as in previous reviews. A quantitative residential post-application assessment was also not conducted as incidental oral exposures are not anticipated and there is no dermal exposure endpoint. Therefore, no residential exposures are applicable for the aggregate risk assessment.

Cumulative exposure. EPA has determined that cyprodinil along with pyrimethanil form a candidate common mechanism group (CMG). This group of

pesticides is considered a candidate CMG because there is sufficient toxicological data to suggest a common pathway. The Agency conducted a screening-level cumulative risk assessment that indicates cumulative dietary and residential aggregate exposures for cyprodinil and pyrimethanil are below the agency's levels of concern. For further information, see the document titled "Anilinopyrimidines. Cumulative Screening Risk Assessment" in docket ID EPA-HQ-OPP-2020-0417. No further cumulative evaluation is necessary for cyprodinil. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework>.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the July 21, 2016 rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 7.7% of the aPAD for children 1 to 2 years old, the group with the highest exposure. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 86% of the cPAD for children 1 to 2 years old, the group with the

highest exposure. There are no residential exposures expected, so the acute dietary risk estimate serves as the acute aggregate risk assessment and the chronic dietary risk estimate serves as the chronic aggregate risk assessment. Cyprodinil is classified as “Not likely to be carcinogenic to humans”, therefore, quantification of cancer risk is not required.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to cyprodinil residues. More detailed information on this action can be found in the “Cyprodinil. Human Health Risk Assessment to Support the Registration of the Proposed New Use on Sugar Apple; and Crop Group Conversions/Expansions to *Brassica*, Leafy Greens, Subgroup 4-16B; Celtuce; Fennel, Florence, Fresh Leaves and Stalk; Kohlrabi; Leaf Petiole Vegetable Subgroup 22B; Leafy Greens Subgroup 4-16A, Except Parsley, Fresh Leaves; Lemon/Lime Subgroup 10-10B; Tropical and Subtropical, Small Fruit, Inedible Peel, Subgroup 24A; and Vegetable, *Brassica*, Head and Stem, Group 5-16” (hereafter “the Cyprodinil Human Health Risk Assessment”) in docket ID EPA-HQ-OPP-2020-0417.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the July 21, 2016 rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

There are no Codex MRLs for residues in/on celtnce, Florence fennel, kohlrabi, members of the lemon/lime subgroup 10-10B, sugar apple, or members of the tropical and subtropical, small fruit, inedible peel, subgroup 24A; therefore, harmonization is not an issue for these commodities.

The U.S. tolerance for residues in/on crop subgroup 22B is harmonized with the Codex MRL for residues in/on celery, a member of crop subgroup 22B.

Codex has established various MRLs for residues in/on crop groups and crop subgroups with overlapping commodities included in crop subgroup 4-16B and crop group 5-16. EPA is not harmonizing the tolerances for residues in/on crop subgroup 4-16B and group 5-16 with the Codex MRLs because the petitioner has requested harmonization with Canadian MRLs rather than Codex MRLs since Canada is a major trading partner for US growers of those commodities.

Codex has established MRLs for residues in/on leafy vegetables (except *Brassica* leafy vegetables) and herbs, which include commodities included in crop subgroup 4-16A, at different levels. The U.S. tolerance for residues in/on leafy greens subgroup 4-16A, except parsley, fresh leaves, is harmonized with the Codex MRL for residues in/on leafy vegetables (except *Brassica* leafy vegetables), which includes lettuce and spinach (the representative commodities for crop subgroup 4-16A) and some other leafy vegetables. The subgroup tolerances are supported by available residue data on the representative commodities and the consistency of labeled use patterns for commodities within subgroup 4-16A; therefore, EPA is leaving the subgroup intact rather than pull individual commodities out to harmonize with Codex.

C. Revisions to Petitioned-For Tolerances

Although the petitioner requested a tolerance for *Brassica*, leafy greens, subgroup 4-16B, except watercress, EPA is establishing the subgroup 4-16B tolerance without the exception. While EPA agrees that a separate tolerance on watercress is appropriate due to

the difference in use patterns for *Brassica*, leafy greens and watercress, the existing separate tolerance for watercress will cover the residues in watercress resulting from use as directed on the label. Because that tolerance is already higher, it will cover residues and there is no need to exclude watercress from the subgroup.

V. Conclusion

Therefore, tolerances are established for residues of cyprodinil in or on *Brassica*, leafy greens, subgroup 4-16B at 10 ppm; Celtuce at 30 ppm; Fennel, Florence, fresh leaves and stalk at 30 ppm; Kohlrabi at 1 ppm; Leaf petiole vegetable subgroup 22B at 30 ppm; Leafy greens subgroup 4-16A, except parsley, fresh leaves at 50 ppm; Lemon/lime subgroup 10-10B at 0.6 ppm; Sugar apple at 4 ppm; Tropical and subtropical, small fruit, inedible peel, subgroup 24A at 2 ppm; and Vegetable, *Brassica*, head and stem, group 5-16 at 1 ppm. Additionally, the following existing tolerances are removed as unnecessary due to the establishment of the above tolerances: *Brassica*, head and stem, subgroup 5A; *Brassica*, leafy greens, subgroup 5B; Leaf petioles subgroup 4B; Leafy greens subgroup 4A; Lemon; Lime; Longan; Lychee; Spanish lime; and Turnip, greens.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act

(PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides, and pests, Reporting and recordkeeping requirements.

Dated: January 20, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.532, amend the table in paragraph (a)(1) by:

- a. Designating the table as Table 1;
- b. Removing the entry for “*Brassica*, head and stem, subgroup 5A”.
- c. Adding in alphabetical order the entry “*Brassica*, leafy greens, subgroup 4-16B”.
- d. Removing the entry for “*Brassica*, leafy greens, subgroup 5B”.
- e. Adding in alphabetical order the entries “Celtuce”; “Fennel, Florence, fresh leaves and stalk” and “Kohlrabi”.
- f. Removing the entry for “Leaf petioles subgroup 4B”.
- g. Adding in alphabetical order the entry “Leaf petiole vegetable subgroup 22B”.
- h. Removing the entry for “Leafy greens subgroup 4A”.
- i. Adding in alphabetical order the entry “Leafy greens subgroup 4-16A, except parsley, fresh leaves”.
- j. Removing the entries for “Lemon” and “Lime”.
- k. Adding in alphabetical order the entry “Lemon/lime subgroup 10-10B”.
- l. Removing the entries for “Longan”; “Lychee”; and “Spanish lime”.
- m. Adding in alphabetical order the entries “Sugar apple”; and “Tropical and subtropical, small fruit, inedible peel, subgroup 24A”.
- n. Removing the entry for “Turnip, greens”.

o. Adding in alphabetical order the entry “Vegetable, *Brassica*, head and stem, group 5-16”.

The additions read as follows:

§ 180.532 Cyprodinil; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * * *	* *
<i>Brassica</i> , leafy greens, subgroup 4-16B	10
* * * * *	* *
Celtuce	30
* * * * *	* *
Fennel, Florence, fresh leaves and stalk	30
* * * * *	* *
Kohlrabi	1
Leaf petiole vegetable subgroup 22B	30
Leafy greens subgroup 4-16A, except parsley, fresh leaves	50
Lemon/lime subgroup 10-10B	0.6
* * * * *	* *
Sugar apple	4
Tropical and subtropical, small fruit, inedible peel, subgroup 24A	2
Vegetable, <i>Brassica</i> , head and stem, group 5-16	1
* * * * *	* *

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